

FTS-HHS FDA

**Moderator: Rita Chappelle
December 17, 2009
8:53 am CT**

Coordinator: Welcome everyone and thank you for standing by. At this time I would like to inform all participants that you will be able to listen only until the question and answer session of today's conference call. If you would like to...

Megan Scott: (Bridget) we can't hear you.

Coordinator: You can't hear me?

Megan Scott: No.

Coordinator: At all?

Megan Scott: Now we can.

Woman: Maybe it's our...

Man: Tell her (unintelligible).

Coordinator: I'm not sure...

((Crosstalk))

Coordinator: Sorry.

Woman: (Unintelligible).

Coordinator: Okay. Just wanted to let all parties know that you'll be able to listen only until the question and answer session of today's conference call. Today's conference is being recorded. If you have any objections, you may disconnect at this time. If you would like to ask a question, please press star 1 on your Touch-Tone phone. And I will now turn the call over to Megan Scott. Thank you. You may begin.

Megan Scott: Thank you (Bridget). Thank you all for joining us on this call today. My name is Megan Scott. I'm in the FDA Media Relations staff. We appreciate you joining us on this briefing for the launch of our new pet health and safety widget.

Our speakers on today's call are going to be Dr. Joshua Sharfstein, Principal Deputy Commissioner of Food and Drug and Dr. Bernadette Dunham, Director of FDA's Center for Veterinary Medicine.

As soon as they finish their opening remarks we are going to open it up for questions. Also on the call with us today is Sanjay Koyani who will be discussing the technical aspects of the widget and other online resources of the FDA.

At this time I would like to turn it over to Dr. Sharfstein.

Joshua Sharfstein: Thank you Megan and thank you to everybody who is on the call. I apologize.

I am calling from a remote location because of some urgent issues that came up but I'm glad I have the chance to call in.

I think today's announcement is an exciting step forward for FDA's transparency and outreach to the pet community on important issues of health and safety.

I'm Josh Sharfstein the Principal Deputy Commissioner. Previous to coming to FDA I was the Commissioner of Health in Baltimore and as part of that job I was the chair of the board of the animal shelter called BARCS in the city.

And over the (unintelligible) I was health commissioner we saw major increases in adoptions and rescues of animals and I really gained an appreciation personally for the interrelationship between pet health and human well-being, both in the ways that pets interact with humans as well as the fact that our health in many ways is linked together.

And I've understood that even better at FDA where many issues of food safety and infectious disease and other contaminants and health issues relate both to pets and to humans. FDA has an incredibly important role (in displaying) pet health and you'll hear about that more from Dr. Dunham of the Center for Veterinary Medicine.

But we have also a lot of information, a lot of important advice and it's very important for FDA to share that with the community that cares for pets. And I think this is an opportunity not only to be able to share that information in a very timely fashion to get feedback on concerns, but also to spread the information from our world using some interactive tools to other people's

worlds on their Web sites and really be able to get tremendous amount of information out to people who really can use it.

So I really want to thank Megan Scott and the communications staff and Dr. Dunham and her team, very dedicated, pet-loving team at CVM, for their work on this and with that I'll turn it back over to you Megan.

Megan Scott: And I will turn it over to Dr. Dunham.

Bernadette Dunham: Well thank you all very much. And thank you Dr. Sharfstein for a very nice introduction to a very exciting opportunity for us to really reach out and embrace the current status of communications through (quote) this new widget and to be able to help folks appreciate all that we do at FDA.

I do agree the transparency is something that we embrace. It's very important that we have an opportunity to reach out and help educate at the same time hear from the public their concerns and their questions as we help you understand and can help you keep you pets healthy.

The FDA is responsible for protecting the public health by assuring the safety and efficacy and the security of many items, human and veterinary drugs, biologic products, medical devices, our nation's food supply, cosmetics, products that emit radiation and tobacco products.

And so today we have an opportunity to choose one of these key areas for you in the first launch of this widget. So this is going to come this time (with regard) our role in the animal health and safety side of FDA.

The Center for Veterinary Medicine evaluates the manufacturer and distribution of food additives and drugs that will be given to animals. It's also

responsible for regulating drugs, devices and food additives given to or used on over 100 million companion animals plus millions of poultry, cattle, swine and minor animal species.

So we have a very diverse portfolio. It's very exciting but more importantly for today's issue, it's reaching out to a (contrary) the public that is very near and dear to me and that is the pet-loving population. And for many of us who have pets we understand how important they are every day to giving us so much love and companionship.

So what we're going to do now is have fun launching and telling you all about how to access this widget. So with this I'm going to turn over now to Sanjay who will help us go through this.

Sanjay Koyani: Great. Thank you Dr. Dunham. Well the pet health and safety widget is available on fda.gov. We're featuring it on our homepage. You can also get it at www.fda.gov/pethealthwidget.

And for those of you who are unfamiliar with widgets, it's basically a small application that we've created that you can embed in either a social network, a blog or a Web site. And our goal is really to allow people to see our health information on a number of different locations in addition to just fda.gov.

What the widget enables you to do is to see a couple of things. One, is it gives you the ability to click on the "tips" tab and you'll basically see pet health stories from FDA, whether it's how to report a pet food complaint or how to protect your pet during a disaster. The other tab is called "updates" and when you click that tab you'll basically get the latest news and safety information from the fda.gov site on animal health and safety.

What you'll see towards the bottom of the widget is the ability to easily grab code that you can cut and paste out of it and then insert that into your Web page, blog or social media channel.

And our goal with a lot of our products is to create once and share many times so that no matter where people go across the digital landscape, they can get to our important information rather than always having to come back to fda.gov directly.

Megan Scott: Great. Thank you Sanjay. And at this time we are going to open the call up to questions. As always please limit yourselves to one question and one follow-up. And at this time (Bridget) we'll be ready to take the first question.

Coordinator: Thank you. At this time if there are questions or comments, please press star 1 on your Touch-Tone phone. Again, that is star 1 on your Touch-Tone phone if you have any questions or comments. We'll wait one moment to see if any questions come into queue.

Megan Scott: Great. Thank you. Quiet bunch of reporters on today's call.

Woman: (Unintelligible).

Coordinator: Okay once again if any of you have any comments or anything that you would like to make, it's star 1 on your Touch-Tone phone. Just one moment it looks like we may have a couple questions coming through.

Our first question will be from (Ben Maskovich), FDA Week. Your line is open.

(Ben Maskovich): Hi. I was just curious if you all are going to expand this widget to any other areas of FDA Oversight or a similar widget?

Bernadette Dunham: Yes. This is the one thing we're very excited about. As I mentioned when I first gave the overview, there's many centers in FDA. And we're hoping - with this successful launch, it's a trial, we'll have a chance to see how it works and hopefully hear your feedback, and then be able to do this further as a way of further reaching out and enhancing communication to the public on many of the centers that we have at FDA dealing with public health. So thank you very much.

(Ben Maskovich): Great. Thanks.

Megan Scott: Thank you. Next question please.

Coordinator: All right. Our next question is from Gina Spadafori, Universal Press. Your line is open.

Gina Spadafori: Yes, thank you. Love seeing the increased transparency and the widget's darn cute, like the kitty. But I guess my concern is even though we've seen a real change in the attitude of the FDA, not so much the attitude I guess, the responsiveness of the FDA in reporting recalls that have been reported by the manufacturers, we're still seeing according to the pet lovers who we talk to some secret recalls - pulling back from the shelves, and also a huge lag time between the time a food is pulled back and the time that the manufacturer either reports it to the FDA or the FDA gets out the information.

I'm assuming the problem is with the manufacturers and as soon as you have the voluntary recall information you put it out. Can you address how this widget would change that? Or would this help address that lag time? We're

seeing recently a September recall that didn't end up on the FDA Web site until November. So, you know, how is this going to fit into that problem?

Bernadette Dunham: Thank you very much for that question and I think you're hitting the nail on the head. We really want to have an opportunity to be able to help educate the public on how we do things and our regulations and how they go forward.

So one list that FDA does provide is primarily made of the Class 1 recall. And a Class 1 recall is one of the most serious categories and constitutes a situation in which there is reasonable probability that the use of or exposure to a volatile product can cause serious adverse health consequences or death. This is true for people or for animals.

And when something like that is under investigation we will work in this case if it's a food product such as a pet food, we work with the company and companies can do voluntary recalls and they can post anything they want on their Web page. For FDA, we get involved then on the investigation side.

So we have our investigators go out and any time any item is under investigation, we team tag and put out the alerts but we need to have our inspectors complete the investigation and at that time then we can go ahead and do the formal posting because this is all under litigation when we do this.

But part and parcel it's most important for us to be able to reach out and give the public an awareness of what is happening and a heads up and working very closely with the companies because they're the ones that will be the folks to help us do the recalls and further reach out and notify you.

So now the widget is going to help us team tag that in a very, very positive outreach way so you're going to see things very quickly. And so we're hoping

by this kind of enhanced transparency and communication we'll better be able to respond and ensure the health of our pets.

Megan Scott: Great. Thank you Gina. Next question.

Coordinator: Thank you. Once again I am showing no questions. At this time as a reminder if there are additional questions or comments you may press star 1 on your Touch-Tone phones at this time. And that is star 1 on your Touch-Tone phones if you have any additional comments or questions you would like to make.

Megan Scott: Okay. I think that will conclude today's teleconference. Thank you all for your participation today. Dr. Dunham, Dr. Sharfstein, Sanjay, thanks so much for taking the time.

A replay of this call will be available in about an hour and it will be up for about three days. If you have any follow-up questions, please don't hesitate to reach out to the Center for Veterinary Medicine. Thanks and have a great day.

Coordinator: That concludes today's conference call. We thank you very much for your participation. You may all disconnect.

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